OCT - 4 2006

510(k) Summary for
Dimension Vista™ RF Flex® reagent cartridge
Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ Protein 2 Control L
Dimension Vista™ Protein 2 Control H

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K062035

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
D-35001
Marburg, Germany

Contact Information: Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: September 11, 2006

2. **Device Name:** Dimension Vista™ Rheumatoid Factors Flex® reagent cartridge (RF)
Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ Protein 2 Control L
Dimension Vista™ Protein 2 Control H

Classification: Class II; Class II; Class I
Product Code: DHR; JIX; JJY
Panel: Immunology (82) and Clinical Chemistry (75)

3. **Identification of the Legally Marketed Device:**

ROCHE Tina-Quant RF II assay - K032535
N Rheumatology Standard SL - K964527
N/T Rheumatology Control SL - K962373

4. **Device Description:**

Dimension Vista™ RF Flex® reagent cartridge
Polystyrene particles coated with an immunocomplex consisting of human immunoglobulin and anti-human IgG from sheep are aggregated when mixed with samples containing RF. These aggregates scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the

respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Dimension Vista™ Protein 2 Calibrator
PROT2 CAL is a liquid, human serum based product containing C-reactive protein and Rheumatoid Factors.

Dimension Vista™ Protein 2 Control L and H
PROT2 CON L and H are liquid, multi-analyte, human serum based products containing C-reactive protein and Rheumatoid Factors.

5. **Device Intended Use:**

Dimension Vista™ RF Flex® reagent cartridge:
The RF method is an *in vitro* diagnostic reagent for the quantitative determination of rheumatoid factors (RF) in human serum and lithium heparin plasma on the Dimension Vista™ System. Measurements of RF are used as an aid in the diagnosis of rheumatoid arthritis.

Dimension Vista™ Protein 2 Calibrator:
PROT2 CAL is an *in vitro* diagnostic product for the calibration of the C-reactive protein (CRP), *high sensitivity* CRP (hsCRP) and Rheumatoid Factors (RF) methods on the Dimension Vista™ System.

Dimension Vista™ Protein 2 Controls L and H:
PROT2 CON L and H are assayed intralaboratory quality controls for the assessment of precision and analytical bias in the determination of C-reactive protein (CRP) and Rheumatoid Factors (RF) on the Dimension Vista™ System.

6. **Medical device to which equivalence is claimed and comparison information:**

The Dimension Vista™ RF Flex® reagent cartridge, Dimension Vista™ Protein 2 Calibrator and Dimension Vista™ Protein 2 Controls L and H are substantially equivalent to the ROCHE Tina-Quant RF II assay (K032535), N Rheumatology Standard SL (K964527) and N/T Rheumatology Control SL (K962373), respectively. The Dimension Vista™ RF assay, like the ROCHE Tina-Quant RF II assay is an *in vitro* diagnostic test for the quantitative determination of Rheumatoid Factors in human serum and heparinized plasma.

7. **Device Performance Characteristics:**

The Dimension Vista™ RF assay was compared to the ROCHE Tina-Quant RF II on the Hitachi 917 Analyzer by evaluating serum samples with concentrations ranging from 10 to 520 IU/ML. Regression analysis of these results yielded the following equation:

Method Comparison Study

	n	Slope	Intercept	Correlation Coefficient
Dimension Vista™ RF	118	0.952	-8.65	0.950

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 4 2006

Dade Behring, Inc.
c/o Ms. Kathleen Dray-Lyons
Regulatory Affairs and Compliance Manager
Glasgow Site
P.O. Box 6101
Newark, DE 19714

Re: k062035
Trade/Device Name: Dimension Vista™ Rheumatoid Factors Flex® reagent cartridge
Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ Protein 2 Control L, Dimension Vista™ Protein 2 Control H
Regulation Number: 21 CFR 866.5775
Regulation Name: Rheumatoid Factor Immunological Test System
Regulatory Class: Class II
Product Code: DHR, JIX, JJY
Dated: July 13, 2006
Received: July 19, 2006

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

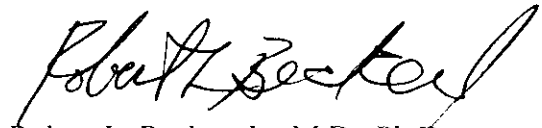
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications Statement

Device Name: **Dimension Vista™ RF Flex® reagent cartridge**
Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ Protein 2 Control L
Dimension Vista™ Protein 2 Control H

Indications for Use:

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Prescription Use __X__ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K062035